

## CLAIMS

What is claimed is:

1. A formulation having particles comprising, by weight, approximately 60% DPPC, approximately 30% insulin and approximately 10% sodium citrate.

2. A formulation having particles comprising, by weight, approximately 40% DPPC, approximately 50% insulin and approximately 10% sodium citrate.

3. The formulation of Claim 1, wherein the particles comprise a mass of from about 1.5 mg and about 20 mg of insulin.

*A 1* 4. The formulation of Claim 1, wherein the particles comprise a mass of about 1.5 mg of insulin per receptacle.

5. The formulation of Claim 1, wherein the particles comprise a mass of about 5 mg of insulin per receptacle.

6. The formulation of Claim 1, wherein the particles comprise a dosage of insulin of between about 42 IU and about 540 IU.

7. The formulation of Claim 6, wherein the particles comprises a dosage of insulin of about 42 IU.

8. The formulation of Claim 6, wherein the particles comprise a dosage of insulin of between about 84 IU and about 294 IU.

9. The formulation of Claim 8, wherein the particles comprise a dosage of insulin of between about 155 IU and about 170 IU.

10. The formulation of Claim 1, wherein the particles have a tap density less than about 0.4 g/cm<sup>3</sup>.

11. The formulation of Claim 10, wherein the particles have a tap density less than about 0.1 g/cm<sup>3</sup>.

12. The formulation of Claim 1, wherein the particles have a median geometric diameter of from between about 5 micrometers and about 30 micrometers.

13. The formulation of Claim 1, wherein the particles have an aerodynamic diameter of from about 1 micrometer to about 5 micrometers.

14. The formulation of Claim 13, wherein the particles have an aerodynamic diameter of from about 1 micrometer to about 3 micrometers.

15. The formulation of Claim 13, wherein the particles have an aerodynamic diameter of from about 3 micrometers to about 5 micrometers.

16. The formulation of Claim 1, wherein the particles further comprise an amino acid.

17. The formulation of Claim 16, wherein the amino acid is leucine, isoleucine, alanine, valine, phenylalanine or any combination thereof.

18. A method for treating a human patient in need of insulin comprising administering pulmonarily to the respiratory tract of a patient in need of

treatment, in a single, breath actuated step an effective amount of particles comprising by weight, approximately 60% DPPC, approximately 30% insulin and approximately 10% sodium citrate, wherein release of the insulin is rapid.

19. A method for treating a human patient in need of insulin comprising administering pulmonarily to the respiratory tract of a patient in need of treatment, in a single, breath actuated step an effective amount of particles comprising by weight, approximately 40% DPPC, approximately 50% insulin and approximately 10% sodium citrate, wherein release of the insulin is rapid.
20. The method of claim 18, wherein the patient in need of treatment has diabetes mellitus.
21. The method of Claim 18, wherein the particles have a mass of from about 1.5 mg and about 20 mg of insulin.
22. The method of Claim 18, wherein the particles comprise a mass of about 1.5 mg of insulin per receptacle.
- A 1*  
*Cont*  
23. The method of Claim 18, wherein the particles comprise a mass of about 5 mg of insulin per receptacle.
24. The method of Claim 18, wherein the particles comprise a dosage of insulin of between about 42 IU and about 540 IU.
25. The method of Claim 24, wherein the particles comprises a dosage of insulin of about 42 IU.

26. The method of Claim 24, wherein the particles comprise a dosage of insulin of between about 84 IU and about 294 IU.

27. The method of Claim 26, wherein the particles comprise a dosage of insulin of between about 155 IU and about 170 IU.

28. The method of Claim 18, wherein the particles have a tap density less than about 0.4 g/cm<sup>3</sup>.

29. The method of Claim 28, wherein the particles have a tap density less than about 0.1 g/cm<sup>3</sup>.

30. The method of Claim 18, wherein the particles have a median geometric diameter from about 5 micrometers and about 30 micrometers.

31. The method of Claim 18, wherein the particles have an aerodynamic diameter of from about 1 micrometer to about 5 micrometers.

32. The method of Claim 31, wherein the particles have an aerodynamic diameter of from about 1 micrometers to about 3 micrometers.

33. The method of Claim 31, wherein the particles have an aerodynamic diameter of from about 3 micrometers to about 5 micrometers.

34. The method of Claim 18, wherein administering the particles pulmonarily includes delivery of the particles to the deep lung.

35. The method of Claim 18, wherein administering the particles pulmonarily includes delivery of the particles to the central airways.

36. The method of Claim 18, wherein administering the particles pulmonarily includes delivery of the particles to the upper airways.

37. The method of Claim 18, wherein the particles further comprise an amino acid.

38. The method of Claim 37, wherein the amino acid is leucine, isoleucine, alanine, valine, phenylalanine or any combination thereof.

39. A method of delivering an effective amount of insulin to the pulmonary system, comprising:

- providing a mass of particles comprising by weight, approximately 60% DPPC, approximately 30% insulin and approximately 10% sodium citrate; and
- administering via simultaneous dispersion and inhalation the particles, from a receptacle having the mass of the particles, to a human subject's respiratory tract, wherein release of the insulin is rapid.

40. A method of delivering an effective amount of insulin to the pulmonary system, comprising:

- providing a mass of particles comprising by weight, approximately 40% DPPC, approximately 50% insulin and approximately 10% sodium citrate; and
- administering via simultaneous dispersion and inhalation the particles, from a receptacle having the mass of the particles, to a human subject's respiratory tract, wherein release of the insulin is rapid.

41. The method of Claim 39, wherein the mass of particles is from about 1.5 mg and about 20 mg of insulin.

A2  
cat

卷之三

- 42. The method of Claim 39, wherein the mass of particles comprises about 1.5 mg of insulin per receptacle.
- 43. The method of Claim 39, wherein the mass of particles comprises about 5 mg of insulin per receptacle.
- 44. The method of Claim 39, wherein the mass of particles comprises a dosage of insulin of between about 42 IU and about 540 IU.
- 45. The method of Claim 44, wherein the mass of particles comprises a dosage of insulin of about 42 IU.
- 46. The method of Claim 44, wherein the mass of particles comprises a dosage of insulin of between about 84 IU and about 294 IU.
- 47. The method of Claim 46, wherein the mass of particles comprises a dosage of insulin of between 155 IU and about 170 IU.
- 48. The method of Claim 39, wherein the particles have a tap density less than about 0.4 g/cm<sup>3</sup>.
- 49. The method of Claim 48, wherein the particles have a tap density less than about 0.1 g/cm<sup>3</sup>.
- 50. The method of Claim 39, wherein the particles have a median geometric diameter of from about 5 micrometers and about 30 micrometers.
- 51. The method of Claim 39, wherein the particles have an aerodynamic diameter of from about 1 micrometer to about 5 micrometers.

A 4

*cox*

52. The method of Claim 50, wherein the particles have an aerodynamic diameter of from about 1 micrometer to about 3 micrometers.

53. The method of Claim 50, wherein the particles have an aerodynamic diameter of from about 3 micrometers to about 5 micrometers.

54. The method of Claim 39, wherein delivery to the pulmonary system includes delivery to the deep lung.

55. The method of Claim 39, wherein delivery to the pulmonary system includes delivery to the central airways.

56. The method of Claim 39, wherein delivery to the pulmonary system includes delivery to the upper airways.

57. The method of Claim 39, wherein the particles further comprise an amino acid.

58. The method of Claim 57, wherein the amino acid is leucine, isoleucine, alanine, valine, phenylalanine or any combination thereof.

59. The formulation of Claim 1, wherein the particles further comprise a low transition temperature phospholipid.

60. The method of Claim 18, wherein the particles further comprise a low transition temperature phospholipid.

DRAFT DRAFT DRAFT DRAFT DRAFT